"By decreasing protocol deviations, SMi Trial improved data quality and reduced the overall number of patients required for trial completion."

Kent Thoelke
EVP & Chief Scientific Officer
PRA Health Sciences

SMi Trial™

Background

A large, global pharmaceutical organization identified one of its investigational CNS drug programs as "the future of the company." The program's multi-arm, Phase II trial was jeopardized by enrollment errors and protocol deviations despite the deployment of hands-on site training. The sponsor selected PRA Health Sciences to help mitigate these risks in their upcoming global Phase III study. In order to scale the trial globally and ensure the quality of the clinical data, PRA implemented SMi Trial™ and exceeded the sponsor's expectations.

Phase II Challenges

- High placebo rates requiring hands-on site training that would be impossible to implement globally
- Errors in subject enrollment into each study arm caused by misdiagnosis of disease subtypes
- Mistakes in dosing, timing of interventions, and measurements as they varied by visit and study arm

Phase III Expectations

- Complete study 6 months sooner
- Streamline enrollment
- Reduce subject costs
- Prevent protocol deviations
- Standardize compliance across 142 global sites and 40 CRAs
- Ensure clinical data quality

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Solution

SMi Trial™

"SMi Trial allowed study teams and site staff to learn on their own time and at their own level, which greatly facilitated the understanding of the therapeutic area and the protocol. This training improved comprehension and the consistency of messaging, and ultimately led to better study conduct."

- Wendy Martin, MD, Senior Medical Director, PRA Health Sciences

Feature	Critical Fix
Interactive, multimedia eLearning focused on key risks of the clinical trial	Delivered modern, engaging protocol education that reduced placebo rates and prevented major mistakes during study execution
Mobile-friendly delivery with just-in-time access	Fought the "forgetting curve" by allowing site staff to reference training materials, including required activities, prior to patient visits
Modular approach that facilitates knowledge retention and includes role-based assignments	Trained the entire study team while tailoring information to each member's role and education
Integrated assessment questions and inspection-ready audit reports	Identified misunderstandings that led to focused interventions by CRAs during site visits
English, Japanese, and Russian localizations	Ensured clear communication across a global study by avoiding language and cultural barriers

Results

FDA and EMA approvals ahead of schedule

- Trial completion 6 months early
- Deviation rates in the top 10% of all studies conducted in the CRO's history
- $100,000s saved in downstream monitoring and additional time-to-market opportunity costs
- Significantly lower placebo rates
- No adverse findings in audits of training, protocol compliance, and patient protection
- No regulatory issues after multiple site and sponsor inspections

About ScienceMedia

ScienceMedia delivers innovative learning solutions to improve clinical competency throughout life sciences R&D, clinical operations, medical affairs, and commercial organizations.